

Remarks

Claims 1, 3-8 and 10-16 are presently pending before the Office. Applicants have amended claims 1, 6, 10, and 14. Claims 2 and 9 have been canceled. No new matter has been added. Support for the amendments can be found throughout the specification.

The Examiner's Action mailed December 13, 2007, and the references cited therein, have been carefully studied by Applicant. The amendments appearing herein and these explanatory remarks are believed to be fully responsive to the Action. Accordingly, it is believed this patent application is in a condition for allowance.

**INFORMALITIES:**

The Examiner objected to claims 1 and 14 due to informalities. Applicant has addressed these informalities and Applicant respectfully requests reconsideration and withdrawal of the objections.

**35 U.S.C. 112 REJECTIONS:**

The Examiner rejected claims 1, 2 (now cancelled), 5-6, and 10-14 under 35 U.S.C. 112 first paragraph as failing to comply with the written description requirement. The Examiner stated that the claims contain subject matter which was not described in the specification.

First, the Examiner rejected claim 1, under 35 U.S.C. 112 as adding a limitation to the claim wherein "adding pulsing steam and heated inert gas into said single chamber to increase chamber pressure by at least 2 inches of mercury and re-evacuating said single chamber by pulling said inert gas from said chamber by 2 inches of mercury to value of first evacuating mercury *to value of first evacuating step,*" whereas the Examiner points to page 3, lines 29-31 wherein it states "*near the value of the initial evacuation.*" Applicant respectfully directs the Examiner to page 3, lines 26-27, wherein it states, "Preferably, enough Nitrogen is pulsed to increase the pressure to about 2 inches

of mercury and *then the same amount of gas* is pulled from the chamber.” The Applicant submits that this phrase can be understood to also include evacuating the mercury to the value of the first evacuating step. However, in an effort to further prosecution of this application, the Applicant has amended claim 1 to read “to or near to the value of the initial evacuation.”

Next, the Examiner pointed to claim 1, line 8 wherein it states, “150 to 550 mg/L” whereas the specification, page 4 line 19 teaches range of “400-550 mg/L”. The Applicant respectfully directs the Examiner to page 6, Example 1, paragraph named “Additional” wherein it gives an example of the gas concentration during gas dwell being a minimum of 150 mg/L. In addition, page 5 line 22-23 indicate that the pressure range “shows the concentration drop from 450mg/L to 150mg/L”. As such, the Applicant respectfully submits that the range of 150-550 mg/L is fully supported by the specification and respectfully submits that the Examiner withdraw his rejection.

Next, the Examiner objected to the recitation of a second overpressure step. The Examiner is correct, there is only one over-pressure step and the claim has been amended accordingly.

Next the Examiner states that the specification only discloses degassing the product with an inert gas and not steam or a gas wash. The Applicant understands the Examiner’s position and has amended claim 1 to clarify the mechanism of degassing. In essence, the inert gas, Nitrogen, pushes the steam that had been injected into the chamber prior to degassing, as well as the sterilant that had been injected during the sterilization step, into the nooks and crannies of the product and product packaging, as stated on page 5, lines 7-10. The sterilant, EtO, has a strong affinity for the water vapor and bonds to the water vapor. During the degassing step, the Nitrogen pulses flush out the bonded molecules of steam and EtO, leaving the product and product packaging sterilant and practically moisture free after degassing.

Next, the Examiner rejected claim 2 stating that ethylene oxide (EtO) is disclosed only as a

sterilant and not as an inert gas. The Applicant has canceled claim 2 and thanks the Examiner for this correction.

Next, the Examiner rejected claim 5 for adding the limitation of including real-time monitoring of the concentration of EtO in the headspace. The Examiner states that the limitation only has support in the specification for monitoring during dwell time. The Applicant respectfully directs the Examiner to page 5, lines 21-23, wherein it states, “Measurements of the headspace concentration of EtO taken while *performing the present invention* show the concentration drop from 450mg/L to 150mg/L in a manner of minutes.” The Applicant respectfully points out that the present invention includes all of the steps described, including, but not limited to “during the dwell time”. The same paragraph states that real-time measurements of the concentration of sterilant gas in the headspace is monitored during dwell time, however, it was not the Applicant’s intention to limit real-time measurement of the gases to during the dwell time, as can be determined by the phrase “measurements of the headspace concentration of EtO taken while *performing the present invention*.”

Next, the Examiner rejected claims 6 and 10 because of the limitation of “pressurizing said single chamber with 3 to 50 inches of mercury.” The Examiner pointed out that the specification on page 6 discloses a wider range. The Applicant thanks the Examiner and has amended the claims accordingly.

Next the Examiner rejected claim 14, stating that the specification only discloses degassing the product with an inert gas and not steam or a gas wash. The Applicant understands the Examiner’s position and has amended claim 14 to clarify the mechanism of degassing. In essence, the inert gas, Nitrogen, pushes the steam that had been injected into the chamber prior to degassing, as well as the sterilant that had been injected during the sterilization step, into the nooks and

crannies of the product and product packaging, as stated on page 5, lines 7-10. The sterilant, EtO, has a strong affinity for the water vapor and bonds to the water vapor. During the degassing step, the Nitrogen pulses flush out the bonded molecules of steam and EtO, leaving the product and product packaging sterilant and practically moisture free after degassing. In other words, the present disclosure injects sterilant gas first and then overlays the inert gas, which provides a dynamic mechanism of shifting the highest sterilant gas concentration (greater than the specification value, i.e. average value) from the load surface to its center thus enhancing sterilant uniformity and hence sterility.

Next, the Examiner rejected claims 1, 2, and 4 for informalities. In response, the Applicant has amended the referenced claims to comply with the requirements of 35 U.S.C. 112, first paragraph and canceled claim 2. The Applicant, therefore, respectfully requests that the Examiner withdraw his rejections with regard to these claims and also withdraw his rejections to all of the referenced claims under 35 U.S.C. 112.

### **35 U.S.C. 103 REJECTIONS**

The Examiner rejected claims 1-4, 6, and 13-16 under 35 U.S.C. 103(a) as being unpatentable over Joslyn (US 4,770,851) in view of Popescu (US 5,464,580). The Examiner also rejected claims 5 and 10 under 35 U.S.C. 103(a) as being unpatentable over Joslyn in view of Popescu, and in further view of Stewart (US 5,882,590). The Examiner rejected claims 11-12 under 35 U.S.C. 103(a) as being unpatentable over Joslyn in view of Popescu, Stewart, and in further view of Kolstad (US 4,973,449). Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Joslyn in view of Popescu and in further view of Kolstad.

The Applicant respectfully traverse the rejections and requests reconsideration. It is evident the Applicant's invention is decidedly different from the teachings of the cited patents.

First, using Joslyn's method of sterilization requires the air and steam to condense on the interstices of the load. (Abstract and claim 1). The present disclosure, however, teaches away from the steam condensing on the product or packaging. As stated on page 5, lines 8-10, "the overpressure ...drives the steam or heated water vapor into the center of the load thereby driving both the heat and ethylene oxide into the most difficult or densest areas of the product packaging configuration." At the temperature and pressure provided within the present application, the steam would not condense. Were the water vapor and sterilant to condense within the nooks and crannies of the product and packaging, even pulsing with the inert gas would not be able to remove the condensed liquid to the degree necessary from the product and product packaging at the temperature and pressures specified. Therefore, because the present disclosure teaches away from Joslyn, the Applicant submits that the present disclosure is patentable over Joslyn. The Examiner's reference to Popescu using Nitrogen as the inert gas used to pulse the sterilant out of the product and packaging does not overcome the fact that Joslyn requires the steam to condense in the product in order to be effective. The present disclosure clearly teaches away from the steam and sterilant condensing in or on the product. Claim 1 has been amended to positively recite this distinction.

Furthermore, as stated above, this method adds steam first and then injects heated inert gas, which provides a dynamic mechanism of delivering/pushing the heat of the steam into the load/product by the inert gas through a pressure gradient between the chamber headspace and the load center. Neither Joslyn's method (USPN 4770851) nor Popescu's (USPN 5464580) provides or discloses such a dynamic mechanism.

In addition, this method injects sterilant gas first and then overlays the inert gas, which provides a dynamic mechanism of shifting the highest sterilant gas concentration (greater than

the specification value, i.e. average value) from the load/product surface to its center, thus enhancing sterility uniformity, and hence sterility. Neither Joslyn's method (USPN 4770851) nor Popescu's (USPN 5464580) provides or discloses such a dynamic mechanism. Popescu's method overlays the inert gas first and then injects sterile gas and therefore, would not provide the dynamic mechanism as mentioned above.


Similarly, in claim 14, the invention claims "pulsing in heated Nitrogen". This method, during the evacuation phase, adds steam first and then injects heated Nitrogen, which provides a dynamic mechanism of delivering/pushing the heat of the steam into the load by the Nitrogen gas through a pressure gradient between the chamber headspace and the load center. Neither Joslyn's method (USPN 4770851) nor Popescu's (USPN 5464580) provides or discloses such a dynamic mechanism.

With this Amendment, it is believed the application is in a condition for allowance and respectfully requests reconsideration, reexamination and allowance of the claims in view of the above-noted amendments and the following remarks.

Applicant believes that no fee is due in connection with the present Amendment C. The Commissioner is, however, authorized to charge any underpayment or credit any overpayment to Deposit Account No. 50-2035.

Should the Examiner be of the opinion a telephone conference would expedite prosecution of the subject application, he is respectfully requested to call the undersigned at the below-listed number.

Respectfully submitted,

By: 

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